COMMENTS OF THE TOBACCO INSTITUTE ON THE DRAFT EPA "FACT SHEET" ON ENVIRONMENTAL TOBACCO SMOKE (ETS)

The Tobacco Institute believes that the "Fact Sheet" could be improved by discussion of the factors set forth in this memorandum. We believe the "Fact Sheet" is deficient in the following respects:

- It exaggerates the contribution of ETS to indoor air pollution, fails to place in perspective other indoor air pollution sources and understates the effectiveness of ventilation in removing ETS.

- It contains a number of incorrect statements, particularly misstatements of the health effects of ETS. This is reflected in the draft's summary of the relevant scientific evidence and its disregard of the findings in numerous studies that are at odds with the conclusions of the draft.

The Draft "Fact Sheet" Exaggerates the Place of ETS in Indoor Air Pollution and Incorrectly Evaluates the Effectiveness of Ventilation in Removing ETS

The proposed "Fact Sheet" is inaccurate in discussing the contribution of ETS to indoor air pollution. The overemphasis on ETS as a contributor to indoor air pollution, coupled with the underestimation of the effectiveness of ventilation in removing ETS, results in a misleading presentation of indoor air pollution issues. This could lead people to ignore the more significant contribution of poorly designed and maintained ventilation systems to the general problem of poor indoor air quality.

2046586464

Source: https://www.industrydocuments.ucsf.edu/docs/qnbk0000

For instance, the "Fact Sheet" is inaccurate in claiming that: "Studies show that in buildings where smoking is permitted, ETS easily dominates pollution in buildings." (p. 2). The "Fact Sheet" relies upon "several [unspecified] studies" for this proposition, as well as the EPA Total Exposure Assessment Methodologies (TEAM) study. The draft "Fact Sheet" concludes by asserting -- plainly without justification -- that, in buildings where smoking is permitted, "ETS contributes 80% to 90% of the pollution present." (p. 2).

EPA has not taken into account its own specific findings as well as conclusions by other government agencies. Initially, we do not find in the TEAM study the conclusion that 80% - 90% of the indoor air pollution in commercial buildings is caused by ETS. Moreover, there are a large number of studies showing that poor ventilation is by far the single most important cause of indoor air pollution, including studies conducted by the National Institute for Occupational Safety and Health (NIOSH). One such study by NIOSH of 203 buildings found that inadequate ventilation was the problem in 48.3 percent of NIOSH investigations, while cigarette smoking was the problem in only 2 percent of the investigations. Melius, J., et al., "Indoor Air Quality -- the NIOSH Experience," 10 Ann. Am. Conf. Gov. Ind. Hyg., 3 (1984) at p. 4. A more recent report by Wallingford, K., "NIOSH Indoor Air Quality Investigations: 1971-1985" supports this conclusion.

2046586465

Source: https://www.industrydocuments.ucsf.edu/docs/qnbk0000

See also, Robertson, G., "Source, Nature and Symptomology of Indoor Air Pollutants;" Proc. Indoor Air Qual. Conf., London, pp. 311-319 (1988). It is thus incorrect to claim that ETS "easily dominates" indoor air pollution in buildings.

Perhaps the most significant omission in the "Fact Sheet" is the failure to take account of the substantial work conducted by EPA in connection with its preparation of the "EPA Indoor Air Quality Implementation Plan" submitted to Congress pursuant to Title IV of SARA, the "Radon Gas and Indoor Air Quality Research Act." Appendix A to the IAQ Implementation Plan, "Preliminary Indoor Air Pollution Information Assessment" (Information Assessment), describes a number of studies undertaken by numerous federal agencies relating to the various sources of indoor air pollution. The "Fact Sheet" has ignored the studies cited by EPA in the Information Assessment.

The studies cited by EPA in the Information Assessment include a CPSC study of unvented space heaters, studies of pollutants emitted from gas stoves, and studies of pollutants emitted from wood burning stoves and fireplaces. In fact, EPA's own "Exposure Profile by Source Prevalence and Use Patterns for Selected Pollutants in the U.S." gives a far more accurate picture of the relative importance of various pollutant sources than the "Fact Sheet." See Information Assessment at pp. 2-5. There EPA found that the number of people potentially exposed to ETS (both smokers and

2046586466

Source: https://www.industrydocuments.ucsf.edu/docs/qnbk0000

nonsmokers) was substantially lower than the number exposed to the same basic pollutants from gas stoves, hot water heaters and furnaces.

The "Fact Sheet's" understatement of the effectiveness of ventilation in removing ETS should also be corrected. The message in the proposed "Fact Sheet" that ventilation cannot effectively remove ETS stands in stark contrast to EPA's own conclusions in the Information Assessment document. In the Information Assessment, EPA states:

> The use of high-efficiency filters or electrostatic devices, either installed in the ductwork of central air handling systems or as portable units, strategically placed, can be effective in removing the PM of ETS. . . .

Similarly, filtration and ventilation have been found sufficient to remove constituents of the gas-phase of ETS, as they have in connection with CO_2 generated by building occupants. See Appendix D to Proposed ASHRAE Standard 62-1981R; Sterling, T.D., et al., "Environmental Tobacco Smoke and Indoor Air Quality in Modern Office Work Environments," 29 J. of Occ. Med., 57 (January 1987). It is therefore incorrect to assert, as does the draft "Fact Sheet," that "the only way to eliminate nonsmokers' exposure to ETS is to remove tobacco smoke completely." (p. 3).

For example, studies of office buildings and aircraft have found marked reductions in nicotine levels in areas where smoking is restricted as compared with areas where

2046586467

Source: https://www.industrydocuments.ucsf.edu/docs/qnbk0000

smoking is allowed. Holcomb, L.C.; "Impact of Environmental Tobacco Smoke on Airline Cabin Air Quality;" Env. Tech. Letters; 6, 509-514 (1988); Sterling, T.D.; "ETS Concentrations under Different Conditions of Ventilation and Smoking Regulation;" Proc. Indoor Air Qual. Conf., London, pp. 89-98 (1988); Oldaker III, G.B., Conrad, F.C.; "Estimation of Effect of Environmental Tobacco Smoke on Air Quality within Passenger Cabins of Commercial Aircraft;" Environ. Sci. Technol.; 21, 994-999 (1987). In some cases, the nicotine levels were below detectable limits. In these studies, contaminants such as CO, CO_2 and respirable suspended particulates were also present and found to have been generated from sources other than ETS. This demonstrates that separating smokers from nonsmokers is an effective way to control exposure to ETS and that there exist concentrations of air contaminants that are not associated with ETS.

Other government reports as well as independent studies by private experts further belie the discussion of the effectiveness of ventilation to remove ETS. The National Research Council recently confirmed the ability of ventilation to reduce pollutants from all sources and further observed that NIOSH investigations most frequently recommend increased ventilation to address indoor air pollution problems. "Policies and Procedures for Control of Indoor Air Quality," Committee on Indoor Air Quality, at p. 70. In the Sterling

2046586468

Source: https://www.industrydocuments.ucsf.edu/docs/qnbk0000

study, supra, p. 57, the ability of ventilation to control for the constituents of ETS was highlighted:

> Ventilation required to remove indoor contaminants produced by the occupants themselves, specifically CO_2 and body odor, will also remove the constituents of ETS. Id. at p. 61.

Similarly, actions by national ventilation standards-setting organizations, including the American Society of Heating, Refrigerating and Air Conditioning Engineers, contradict the recommendations in the "Fact Sheet." In proposed ASHRAE Standard 62-1981R, the standard clearly contemplates ventilation as a means by which to remove ETS constituents. The table within the standard prescribing ventilation rates for various indoor spaces accounts for the presence of ETS. It is significant to note that, in revising the existing standard (62-1981), which prescribed separate ventilation rates for smoking and nonsmoking spaces, the Revision Committee focused upon the need to control the presence of other indoor air contaminants such as CO_2 and respirable suspended particulates in setting the new, higher ventilation rates. The Committee was concerned that the existing 5 cfm/occ recommended rate for nonsmoking areas was insufficient to control for commonly found contaminants (such as body-odor and occupant-generated CO_2) and accordingly raised the prescribed minimum rate for all areas if not otherwise identified in the rate table. See Appendix D to Proposed ASHRAE Standard 62-1981R ("Rationale for Minimum

2046586469

Source: https://www.industrydocuments.ucsf.edu/docs/qnbk0000

Physiological Requirements for Respiration Air Based on CO_2 Concentration"); Indoor Air Quality Update, Vol. 1, No. 1, at 12-13, (Cutter Information Corp., September 1988).

Although the ventilation rate table sets higher ventilation rates for "smoking lounges," the proposed rate for these areas is 60 cfm/occ -- far less than the exaggerated claim in the "Fact Sheet" that "more than 4,000 cubic feet of ventilation air per minute per smoker" would be required to remove tobacco smoke particles generated by two smokers within a 1,000 square foot office. (p. 3). Only one individual, James Repace, has recommended these exaggerated rates of ventilation to control ETS, and his recommendation was not adopted by the ASHRAE Revision Committee charged with drafting the new ASHRAE standard. The ASHRAE Revision Committee chose not to recommend unreasonably high rates of ventilation to control ETS, deciding instead that the rates prescribed in the ventilation rate table would adequately assure acceptable indoor air quality.

The Draft "Fact Sheet" Misstates the Health Effects of ETS

The linchpin of the "Fact Sheet" is the allegation that exposure to ETS can cause cancer, heart disease and respiratory disease. The potential adverse health effects of ETS have been extensively studied, and there is a large body of relevant scientific literature. The draft "Fact Sheet"

2046586470

Source: https://www.industrydocuments.ucsf.edu/docs/qnbk0000

contains an incomplete and inadequate summary of the available scientific evidence.

First, the "Fact Sheet" contains repeated unsubstantiated claims that exposure to ETS causes heart disease. In fact, no link has been shown between ETS and cardiovascular or heart disease. Both the Surgeon General and the National Academy of Sciences (NAS) found that available studies preclude any firm conclusion about the relationship between exposure to ETS and cardiovascular disease and that further studies are needed to determine whether any real link exists. (Surgeon General's Report, p. 14; NAS Report, p. 11).

Second, the claim in the introduction to the "Fact Sheet" that ETS "has been linked to . . . respiratory disease" is also incorrect. The NAS concluded that pulmonary effects in normal adults are likely to reflect the cumulative burden of many environmental and occupational exposures and other insults to the lung and that it is difficult to attribute any portion of the effect solely to ETS. (NAS Report, p. 10). The Surgeon General concluded that "a previously healthy individual would not develop chronic lung disease solely on the basis of involuntary tobacco smoke exposure in adult life". (Surgeon General's Report, p. 62). There are numerous other studies, not discussed or cited in the "Fact Sheet", that fail to demonstrate an adverse effect of ETS on pulmonary function.

2046586471

Source: https://www.industrydocuments.ucsf.edu/docs/qnbk0000

Third, the "Fact Sheet" states that "[t]obacco smoke is a mutagen, which means it can cause permanent, often harmful, changes in the genetic material of cells" (p. 2). It is important to note, however, that most mutagenicity tests on tobacco smoke have been performed on mainstream or sidestream smoke, and not ETS. This led the NAS to conclude that "[s]ufficient data are not available to assess the relative genotoxicity and toxicity of whole ETS." (NAS Report, p. 59). In any event, mutagenic substances are ubiquitous in the environment and the food supply, and the possible presence of mutagens in tobacco smoke has no direct public health significance.

Finally, the "Fact Sheet" contains a selective and inadequate treatment of the complex issue of ETS and lung cancer. The "Fact Sheet" states that there is a consensus among three government committees that "passive smoking significantly increases the risk of lung cancer in adults," and it contains a single quote from the Surgeon General's Report attributing to ETS a substantial number of lung cancer deaths among nonsmokers. There is no recognition of, or reference in the "Fact Sheet" to, other pertinent scientific publications, important qualifying statements in the Surgeon General's and NAS Reports and different conclusions contained in reviews by other scientists. The "Fact Sheet" treats the purported relationship between ETS and lung cancer as clear and irrefutable. This is incorrect.

2046586472

Source: https://www.industrydocuments.ucsf.edu/docs/qnbk0000

A careful review of the extensive scientific literature on ETS discloses that the alleged danger of lung cancer has not been substantiated. Both the Surgeon General and NAS Reports emphasize critical limitations on their finding of a possible connection between exposure to ETS and lung cancer. The "Fact Sheet" contains no discussion of these limitations.

The "Fact Sheet" also fails to note that even the limited conclusions of the Surgeon General and NAS Reports have been strongly criticized and that other reviewers have reached different conclusions from the same data. Viewing the same evidence considered by the NAS and Surgeon General, the International Agency for Research on Cancer of the World Health Organization concluded, also in late 1986, that the available evidence is equally consistent with a finding of an increase in risk or an absence of risk.1/ Moreover, there are a number of other studies and reviews, published since 1986, that contradict the findings of the Surgeon General and NAS Reports with respect to the purported relationship between ETS and lung cancer.2/

1/ World Health Organization, International Agency for Research on Cancer, IARC Monograph on the Evaluation of the Carcinogenic Risk of Chemicals to Humans: Tobacco Smoking, vol. 38, p. 308 (1986).

2/ Adlkofer, F., G. Scherer, R. Wenel-Hartung, H. Brune and C. Thomas; "Exposure of Hamsters and Rats to Sidestream Smoke of Cigarettes; Preliminary results of a 90-day-Inhalation Study;" Proc. Indoor Amb. Air Qual. Conf.; London, pp. 252-258

(footnote cont'd)

2046586473

Source: https://www.industrydocuments.ucsf.edu/docs/qnbk0000

It is important that the "Fact Sheet" be revised to recognize the substantial controversy and uncertainty surrounding the purported relationship between ETS and lung cancer.

The Draft "Fact Sheet" Contains Other Unsupported Claims and Inappropriate Language

The "Fact Sheet" also contains a number of other generalizations and unsubstantiated statements that have no proper place in a government publication that is designed to be a factual unbiased reference document. The "Fact Sheet" should be confined to proven facts, described in fair and balanced terms.

For example, it is inaccurate to state that tobacco contains "unknown additives" (p. 1). In fact, pursuant to federal law, cigarette manufacturers are required to identify and report all ingredients in cigarettes to the U.S. Department of Health and Human Services. This comprehensive list is updated annually.

The "Fact Sheet" contends that tobacco smoke produces over 4,700 compounds, many of which have been shown

---

(footnote cont'd)

(1988); Arundel, A., Sterling, T., Weinkam, J., "Exposure and Risk-based estimates of Never Smoked Lung Cancer Deaths in the U.S. in 1980, from Exposure to ETS;" Proc. Indoor Amb. Air Qual. Conf., London, pp. 242-250 (1988); Vandenbrocke, J. P.; "Passive Smoking and Lung Cancer: A Publication Bias?"; Br. Med. J.; pp. 296, 391-391 (1988).

2046589474

Source: https://www.industrydocuments.ucsf.edu/docs/qnbk0000

to be highly toxic. In fact, most of the compounds that have been measured in mainstream tobacco smoke have not been documented to exist in ETS, and the vast majority of substances found in ETS are produced by many other sources as well, including space heaters, gas stoves, insulation, carpets, cleaning fluids, and paints. Moreover, many studies that have attempted to measure specific components of ETS in the air have found trivial or nondetectable levels.

Surveys by the tobacco industry have not "documented" that "an overwhelming majority" of people support restrictions on smoking in public (p. 3). Conversely, these surveys demonstrated that smokers and nonsmokers alike, rather than supporting the imposition of smoking restrictions, prefer that common sense and courtesy govern relationships between smokers and nonsmokers. The surveys also show that a substantial portion of the public views governmentally-mandated public and workplace smoking restrictions as intrusive, burdensome and unworkable.

Other examples of inappropriate language in the "Fact Sheet" include the description of a cigarette as "a tiny chemical factory" (p. 1) and reference to an indoor environment containing ETS as "toxic air" (p. 3). Also, the "Fact Sheet" incorrectly states that "[i]n 1985 evidence that ETS is toxic became so compelling that three U.S. scientific committees were independently convened to consider the public health implications of passive smoking" (p. 1). The committees were convened because questions had been raised

2046586475

Source: https://www.industrydocuments.ucsf.edu/docs/qnbk0000

about ETS, not because evidence that ETS is toxic became compelling.3/

In summary, the draft "Fact Sheet" taken as a whole is one-sided and conclusive about an issue which remains uncertain and, at most, controversial. Publication without substantial modification would seem to call into question the neutrality, integrity and credibility of the Agency.

3/ The "Fact Sheet" also contends that "the nicotine in cigarettes is as addictive as many other drugs" (p. 4). This allegation is gratuitous and inappropriate in a reference document on ETS. Moreover, the 1988 Surgeon General's report on this issue is largely a political document, which is not supported by convincing scientific evidence.

2046586476

Source: https://www.industrydocuments.ucsf.edu/docs/qnbk0000

THIS DOCUMENT IS CALLED G:\DW4\AXELROD2.DOC

KEEP THIS SHEET WITH THIS DOCUMENT AT ALL TIMES IN ORDER TO IDENTIFY ITS LOCATION ON THE COMPUTER.

2046586477

Source: https://www.industrydocuments.ucsf.edu/docs/qnbk0000